

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/576,597 05/22/00 VOORHEES

J 1718-009A

HM22/1106
HOPGOOD CALIMAFDE KALIL & JUDLOWE LLP
60 EAST 42ND STREET
NEW YORK NY 10165

EXAMINER

KIM, V

ART UNIT

PAPER NUMBER

1614

DATE MAILED:

11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application N .

09/576,597

Applicant(s)

VOORHEES ET AL.

Examiner

Vickie Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1 and 3-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Status of Application

1. The amendment and declaration filed september 17, 2001 are properly entered. The claims 1, 3-9, 18-19 and 21 has amended, and claim 20 is added. Claim 2 has been canceled. The response to the remarks and declaration will not be included in this instant office action because this office action is subject to restriction requirement.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 3-9, 18-19 and 21, drawn to a composition comprising a non-retinoid, non-antioxidant inhibitor of a dermal matrix-degrading enzyme, selected from AP-1 inhibitors, NF-kB inhibitors, elastase inhibitors, adhesion antagonists and mixtures thereof; and an active ingredient selected from comedolytics, anti-inflammatories, retinoids, glucocorticoids, and compatible mixtures thereof, classified in class 514, subclass variable based on the species. It is noted that claims 18-19 are improper method claims where the claim 1 they are dependent on is composition claim and the claims 18-19 fail to describe any further method limitation rather than constitution of composition. It is noted that amending claims 18-19 into a method claims will be subject to further restriction requirement.
 - II. Claim 20, drawn to a composition comprising a combination of a neutrophil elastase inhibitor and an active ingredient selected from the

Art Unit: 1614

group consisting of comedolytics, antibacterials, anti-inflammatories, retinoids, glucocorticoids, and compatible mixtures thereof, classified in class 514, subclass variable based on the species.

- III. Claims 10-17, drawn to a method of treating acne comprising the steps of: orally administering an active ingredient for the treatment of acne and topically administering a non-retinoid, non-glucocorticoid inhibitor of a dermal matrix degrading enzyme to acne affected skin, classified in class 514, subclass 859.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I-II and III are related as product and process of use and/or unrelated.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Acne treatment could be achieved by materially different product. For example 5-alpha reductase inhibitors(e.g. progesterone, spirono-lactone) are effectively used in acne treatment. In addition to that these inventions may not be related to each other because the composition which the claims 10-17 require could be different from composition of the invention I or II. For instance, invention I requires non-antioxidant mmp inhibitors where invention III requires mmp inhibitors including one having anti-oxidant feature.

2. Inventions I and II are also unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

Art Unit: 1614

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Claim 1 requires non-antioxidant mmp inhibitor whereas claim 20 requires mmp inhibitors including antioxidant mmp inhibitors.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, the search required for each group is not same, wherein a reference which anticipates the invention of Group I would not render the invention of Group II or III obvious, absent ancillary art, restriction for examination purposes as indicated is proper.

3. It is noted that they were previously examined on the merits previously, it is still proper to make the restriction requirement if there is distinctness and independence any time before final action, even though the inventions were grouped together in the parent application. 37 CFR 1.142(a), see MPEP 811-811.04. Restriction requirement is necessary for the complete and accurate examination. Because the inventions are distinct for the reasons set forth above and have acquired a separate status in the art and the search required for each group is not same, the search of entire groups and/or genus in the non-patent literature(especially, non-patent literature) and database search (a significant part of a thorough examination) would be burdensome, it is undue burden for examiner for the accurate and complete examination.

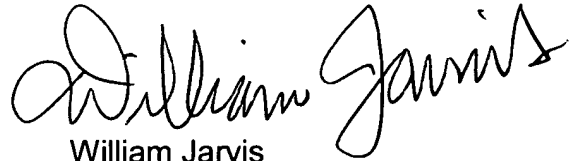
4. Claims 1 and 3-21 are subject to restriction requirement.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Tuesday-Friday: 8AM-6:30PM) and Fax number is (703) 746-3165.

Art Unit: 1614

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
November 1, 2001

A handwritten signature in black ink, reading "William Jarvis". The signature is written in a cursive, flowing style with a large initial "W".

William Jarvis
Primary examiner
Art unit 1614